K011810

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510(k) Summary
Orthogenesis LPS Proximal Tibial Replacement

DePuy, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581

A. Contact Person:

Janet G. Johnson, RAC
Group Leader, Regulatory Submissions
(219) 371-4907

B. Device Information:

Proprietary Name:	Orthogenesis LPS Proximal Tibial Replacement and Orthogenesis LPS Tibial Bearing
Common Name:	Proximal Tibial Replacement Prosthesis
Classification Name and Regulatory Class:	Knee joint femorotibial metal/polymer constrained cemented prosthesis: Class II per 21 CFR §888.3510
Product Code:	87 KRO

C. Indications for Use:

The Orthogenesis LPS is intended for use in replacement of the mid-shaft or intercalary portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and restoration. Specific diagnostic indications for use include:

- metastatic diseases (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection(s) and replacement(s) of the proximal and/or distal femur;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement of the proximal and/or distal femur;
- patients suffering from severe arthropathy of the hip and/or knee that does not respond to any conservative therapy or better alternative surgical treatment;
- revision cases requiring extensive resection(s) and replacements of the proximal, distal or total femur or proximal tibia.

The distal femoral and tibial components, tibial stems and non-porous coated femoral stems are intended for cemented use only.

D. Device Description:

The Orthogenesis LPS Proximal Tibial Replacement system is designed to be implanted for the replacement of the proximal tibia. Unlike primary knee systems, this system is used when the amount of resection and restoration is extreme (e.g. in oncology cases, endstage revision). It consists of a titanium tibial replacement, a polyethylene tibial bearing component, Orthogenesis LPS stems and Segments.

E. Substantial Equivalence:

The substantial equivalence of the Orthogenesis LPS Proximal Tibial Replacement is substantiated by its similarity in indications for use, design, materials, sterilization and packaging to the S-ROM Noiles Rotating Hinge Knee (K896048 and K905810), and the Orthogenesis LPS system.

The determination of substantial equivalence for this device was based on a detailed device description, product testing and conformance with voluntary performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2001

Ms. Janet G. Johnson
Group Leader, Regulatory Submissions
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K011810
Trade Name: Orthogenesis LPS Proximal Tibial Replacement System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: June 8, 2001
Received: June 11, 2001

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

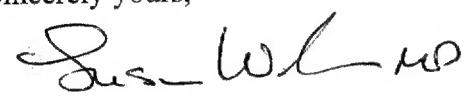
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K011810

Device Name **Orthogenesis LPS Proximal Tibial Replacement**

Indications for Use

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(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011810